MENTAL HEALTH—Methods and Concepts

PMH46

THE SENSITIVITY TO CHANGE OF THE HAMILTON (HAMD) AND THE MONTGOMERY-ASBERG (MADRS) SCALES AS OUTCOME MEASURES IN ANTIDEPRESSANT TRIALS

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OBJECTIVES: To compare the sensitivity to change of the Hamilton Depression Rating Scale (HAMD) and the Montgomery-Åsberg Depression Rating Scale (MADRS) as outcome measures in antidepressant randomised controlled trials (RCTs). **METHODS:** Data come from 2 RCTs (studies A and B) which assessed the efficacy of SSRIs plus pindolol or plus placebo in patients with Major Depression (MD). Study B recruited treatment resistant patients. Both studies included the HAMD and the MADRS as outcome measures. Study A did 10 follow-up measurements (since day 0 to day 42). Study B did 3 follow-up measurements (since day 0 to day 10). Standardised estimates for the change in the severity of depression since day 0 were calculated by a within-group effect size (dw) which accounted for the correlation between measurement times. **RESULTS:** Study A showed a decreasing curvilinear pattern for the HAMD effect sizes (0, –0.55, –0.96, –1.25, –1.53, –1.97, –2.27, –2.15, –2.41, –2.57) which overlapped perfectly with the MADRS estimates (0, –0.56, –0.95, –1.23, –1.56, –1.88, –2.13, –2.17, –2.45, –2.64). Similar pattern was obtained in study B (HAMD: 0, –0.32, –0.62; MADRS: 0, –0.22, –0.52). Additionally, our estimates point to a reliable decrease of the severity of depression even since the first post-baseline measurement (study A, HAMD dw = –0.55 [95% CI = –0.73 to –0.37], MADRS dw = –0.56 [95% CI = –0.74 to –0.38]; study B, HAMD dw = –0.32 [95% CI = –0.52 to –0.11], MADRS dw = –0.22 [95% CI = –0.39 to –0.05]). **CONCLUSION:** Contrary to common beliefs, the HAMD shows an indistinguishable pattern of change from the one obtained with the MADRS, either in common MD populations (study A), or in treatment resistant patients (study B). Also, reliable symptomatic changes seem to appear early on in the course of an antidepressant treatment.

PMH47

DEVELOPING COST-EFFECTIVE FORMULARIES: IMPLICATIONS FOR NEW ATYPICAL ANTIPSYCHOTICS

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OBJECTIVES: Investigate the impact of paliperidone extended-release tablets (paliperidone ER), a newly available oral antipsychotic agent, on a health care formulary from a payer's perspective using a hybrid cost-effectiveness/budget impact approach. **METHODS:** An atypical oral antipsychotic formulary containing risperidone, olanzapine, aripiprazole, quetiapine and ziprasidone was compared to a formulary including the same 5 oral atypicals with the addition of paliperidone ER. Total medical costs and number of re-hospitalization stays were derived from Pharmetrics, a US outpatient insurance claims database with regionally representative coverage. Patients diagnosed with schizophrenia (ICD-9-CM code) in the year prior to initiating a new antipsychotic treatment with 1 full year retrospective and prospective data between January 2002-March 2005 were included. Marketshare was based on IMS Health NDTI MAT ending June 2006. Paliperidone ER was assumed to attain 10% utilization, comparable to latest market entrant. Costs included all schizophrenia-related inpatient and outpatient costs, and re-hospitalization stays in the one year following initiation of treatment. Treatment effect was quantified by adjusting observed values for each atypical for potential confounders including patient characteristics, prior hospitalizations and co-morbidity using generalized gamma regression (GLM). The adjusted outcomes of risperidone and olanzapine were used to simulate the costs and effects of paliperidone ER. Sensitivity analyses were performed on key assumptions and nonparametric bootstrapping was applied to observed data. **RESULTS:** An estimated $121 per patient in total annual medical cost savings (95% CI: 35.11–206.27) could be achieved with the addition of paliperidone ER to the formulary. Assuming a hypothetical cohort of 10,000 patients, this translates into yearly savings of $1.2 million. **CONCLUSION:** The addition of a new agent with similar efficacy and tolerability profile as paliperidone ER, may lead to a more cost-effective formulary.

PMH48

IMPACT OF COMORBIDITY ON EQ-5D: A STUDY OF HEALTH-RELATED QUALITY OF LIFE IN DEPRESSION IN A GENERAL POPULATION SURVEY

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OBJECTIVES: The existence of somatic and psychiatric comorbidity among patients with depressive disorder is well-known and may influence estimates of health-related quality of life (HrQoL) in depression. This study reports on the effect of comorbidity on self-reported EQ-5D in the general population. **METHODS:** Data from the US Medical Expenditures Panel Study (MEPS) 2003 was used. A weighted linear regression model was constructed to allow for its complex sampling design. Socio-economic covariates were included in the model, dichotomized (any diagnosis vs no diagnosis) comorbidity variables based on ICD-9 chapters were then added. The effects of major chronic diseases were analyzed separately as comorbidity variables. Separate models were constructed for men and women. **RESULTS:** The $EQ\text{-}5D_{index}$ adjusted for age and depression was 0.902 for men and 0.887 for women; depression had a disutility of 0.257 for men and 0.207 for women. Adding socio-economic covariates yielded a value for EQ-5D of 0.978 and 0.987 respectively, the disutility of depression decreased to 0.246 for men and 0.172 for women. Among disease conditions that contributed significantly to the estimate of EQ-5D and disutility for depression in both genders were other psychiatric conditions, diabetes, migraine and other neurologic conditions, cardiovascular disease and musculoskeletal diseases. For women only, ischaemic heart disease influenced the model significantly while thyroid diseases had a significant influence for men only. The final disutility of depression in the model was 0.154 for men and 0.115 for women. **CONCLUSION:** A generalized estimate of the disutility of depression in the population for use in pharmacoeconomic studies may be difficult to obtain due to the somatic and psychiatric comorbidity in these patients. The comorbidity has a significant influence on the population disutility estimate for depression.